Cheryl

Paper No. 35

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER J. DUTTON, STEPHEN P. GIBSON and SHIH-JEN E. LEE

Appeal No. 93-1807
Application 07/647,674[1]

ON BRIEF

Before WILLIAM F. SMITH, GRON, and ELLIS, ***Administrative Patent Judges.***

ELLIS, ***Administrative Patent Judge.***

DECISION ON APPEAL

This is an appeal from the final rejection of claim 10, the only claim pending in the application.

[1] Application for patent filed January 25, 1991. According to applicants, this application is a continuation of application 07/249,749, filed September 27, 1988, now abandoned. Applicants also claim priority under 35 U.S.C. § 119 based on the November 14, 1987, filing date of United Kingdom application 1987/26730.

Claim 10 is attached as an appendix to this decision.

The only reference relied on by the examiner is:

Gibson et al. (Gibson)
European Patent Application(EPA `731) 214,731 Mar. 18, 1987

In the Answer, claim 10 was provisionally rejected under the judicially-created doctrine of obviousness-type double patenting and under 35 U.S.C. § 103 as being unpatentable over claims 5-15 of application 07/660,971. However, because application 07/660,971 subsequently issued as U.S. Patent No. 5,234,831,[2] the rejections are no longer provisional. In addition, we point out that the patent contains only two claims. Therefore, for purposes of this appeal, we have considered the patentabilty issues raised by the examiner with respect to the present claims as being directed to the subject matter of patented claims 1 and 2.

Claim 10 also stands rejected under 35 U.S.C. § 103 as being unpatentable over Gibson.

We ***reverse***.

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[2] Application 07/660,971, now, U.S. Patent 5,234,831, issued August 10, 1993, to Hafner ***et al***. (Hafner) and is assigned to Pfizer Inc., New York. The applicants of issued application 07/660,971 claimed priority under 35 U.S.C. § 120 based on Application 07/126,650, filed December 1, 1987, abandoned, and based in-part on Application 07/006,512, filed January 23, 1987, abandoned.

Background

The present invention is directed to a method of producing an avermectin using either one of two novel mutant strains of ***Streptomyces avermitilis***, ATCC 53567 or ATCC 53568. The specification discloses that when fermented in the presence of a carboxylic acid of the formula $R^2CH_2CO_2H$,[3] a salt, an ester, an amide, or an oxidative precursor thereof, the present mutants produce "novel avermectin derivatives, not previously obtainable, wherein the C-25 substituent is linked by an unbranched (primary) carbon atom." Specification, p. 2, lines 17-21; p. 5, line 19 to p. 6, line 1. The specification further discloses that "the novel compounds are highly active antiparasitic agents having particular utility as anthelmintics, ectoparasiticides, insecticides and acaricides." Specification, p. 2, lines 21-23.

The Obvious-Type, Double Patenting Rejection

We note the examiner's remarks on pp. 3-4 of the Answer, in reference to the present application and claims 5 through 15 of application 07/660,991 that:

[3] R^2 is specifically defined in the specification, p. 3, line 5- p. 4, line 5. See also, claim 10, attached as an appendix to this decision.

> the invention of the copending application shows a method for forming avermectin derivatives wherein an alpha-branched carboxylic acid is added to the fermentation medium while the instant invention shows a method for forming an avermectin derivative wherein a carboxylic acid of the formula R_2CH_2COOH is added to the fermentation medium. Hence the carboxylic acid added appears to differ by an alpha substitution i.e. $R\text{-}CH_2CHOOH$ [sic, $R\text{-}CH_2COOH$] as opposed to R-HCHOOH [sic, $R\text{-}CH(CH_3)\text{-}COOH$].
>
> Patentable distinction is not seen as it would have been a matter of obvious choice to replace a methyl group with a hydrogen or replace a hydrogen with a methyl group on the carboxylic acid, or derivative thereof, added to the fermentation medium.

In the case before us, however, we need not pass on the merits of these statements since they have been rendered moot by the issuance of application 07/660,971 as U.S. Patent No. 5,234,831. We direct attention to the fact that claims 5 through 15 of the "copending application" no longer exist in form or substance. The patent has only two claims which are directed to a mutant microorganism, ***S. avermitilis*** ATCC 53692.[4] Not only are the present claims directed to a method of producing avermectin,

[4] U.S. Patent No. 5,234,831 has two claims which read as follows:
1. ***Streptomyces avermitilis*** having all of the characteristics of ATCC 53692.
2. ***Streptomyces avermitilis*** ATCC 53692.

but the claimed method employs two different mutant strains of *Streptomyces avermitilis; i.e.*, ATCC 53567 or 53568.

Accordingly, we reverse the provisional double-patenting rejection.

The Rejection under 35 U.S.C. § 103

As to the rejection of claim 10 under 35 U.S.C. § 103 over Hafner, we note the examiner's holding on p. 4 of Paper No. 25, that Hafner constitutes prior art under 35 U.S.C. § 102(e). However, absent any explanation, the factual basis for this holding is unclear.[5] That is, the examiner has not indicated whether the applicants here are entitled to their claim for priority under 35 U.S.C. § 119 for the full scope of the subject matter of claim 10 and what subject matter described in Hafner is entitled to the January 23, 1987, filing date of Hafner's grandparent. These determinations are important issues since

[5] We direct attention to M.P.E.P. § 201.15 which states that:

> If the priority papers are already in the file when the examiner finds a reference with the intervening effective date, the examiner will study the papers, if they are in the English language, to determine if the applicant is entitled to their date. If the applicant is found to be entitled to the date, the reference is simply not used but may be cited to applicant on form PTO-892. If the applicant is found not entitled to the date, the unpatentable claims are rejected on the reference ***with an explanation*** [emphasis added].

Hafner is available as prior art under 35 U.S.C. § 102(e) only ~~under certain circumstances. For example, if~~ Hafner is not entitled to the benefit of the filing date of the listed grandparent application under 35 U.S.C. § 120, then Hafner is prior art ***only*** if applicants are not entitled to the benefit of the listed prior foreign application under 35 U.S.C. § 119. Conversely, if this application is entitled to benefit under 35 U.S.C. § 119, Hafner is prior art only if it ***is*** entitled to the benefit of the filing date of the grandparent application under 35 U.S.C. § 120.

In their responses (Paper No. 27, filed May 5, 1992, and the Appeal Brief), the appellants only argue that Hafner fails to teach or suggest (1) the present mutants ***S. avermitilis***, ATCC 53567 or 53568, (2) a method of fermenting the claimed microorganisms in the presence of a non-alpha-branched carboxylic acid, and (3) the production an avermectin wherein the C-25 substituent is not alpha-branched. Here, we find that argument (1) is dispositive of the issue of obviousness. Therefore, we need not remand the application to the examiner to determine the priority date of the claimed subject matter ***vis à vis*** the priority date of the subject matter disclosed by Hafner; ***i.e.***,

whether Hafner is, in fact, available as prior art. Nor do we need to reach the merits of arguments (2) and (3). That is, if we assume, arguendo, that Hafner constitutes prior art, we agree with the appellants that the examiner has not explained how the patent would have suggested to one of ordinary skill in the art the claimed method of making avermectin using the present mutants, ***S. avermitilis***, ATCC 53567 and 53568.

Accordingly, the provisional rejection under 35 U.S.C. § 103 over Hafner is reversed.

Rejection under 35 U.S.C. § 103 over Gibson

Gibson is said to disclose a method of producing avermectin having a novel substituent group at the 25-position which comprises fermenting the microorganism ***S. avermitilis*** (ATCC 31267, 31271, or 31272) in the presence of a "broad range of carboxylic acids as defined by R^2CO_2H."[6] Gibson, p. 5, last para. Exemplary acids are listed, each of which is an alpha-branched carboxylic acid. Gibson, sentence bridging pp. 5 and 6.

The examiner argues that, like the present application, Gibson discloses a method of producing avermectin by fermenting a

[6] R^2 is defined on p. 2 of Gibson as "an alpha-branched" carboxylic acid.

strain of ***S. avermitilis*** in the presence of carboxylic acid. Answer, p. 4. The examiner acknowledges that the present invention is directed to the use of a non-alpha-branched carboxylic acid; whereas, the prior art teaches the use of an alpha-branched carboxylic acid. Nevertheless, the examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to include any carboxylic acid in the process of the prior art." ***Id.***, sentence bridging pp. 4 and 5. According to the examiner, one of ordinary skill in the art "would have had a reasonable expectation that when RCH_2CO_2H was substituted for RCO_2H in a fermentation process, a product containing $-CH_2R$ group instead of -R group would be formed because closely related carboxyl acids ***i.e.***, RCH_2CO_2H and RCO_2H would be expected to behave in a similar manner in a fermentation process." ***Id.***, p. 8.

As we understand it, the examiner's position is premised on that body of case law which has held that the structural similarity between chemical isomers and homologues can give rise to a ***prima facie*** case of obviousness "where the prior art gives reason or motivation to make the claimed compositions." ***In re***

Dillon, 919 F.2d 688, 693, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (*en banc*), *cert. denied*, 500 U.S. 904 (1991). *See also*, *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979) ("[a]n obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties"). Even if we were to agree that the applied prior art would have provided ample motivation to make the claimed compound using a non-alpha-branched carboxylic acid, we could not affirm this rejection. Here, we find that in reaching her conclusion, the examiner has overlooked one crucial claim limitation. Claim 10 requires the use of specific mutants; *i.e.*, *S. avermitilis* ATCC 53567 or *S. avermitilis* ATCC 53568. The examiner has not provided any evidence that the present *S. avermitilis* mutants would have been expected to utilize non-alpha-branched carboxylic acid derivatives in the same, or substantially the same, manner as the *S. avermitilis* mutants ATCC 31267, 31271, and 31272 described by Gibson utilize alpha-branched carboxylic acid derivatives. Accordingly, we do not find the examiner has provided, in the first instance, a factual basis upon which to

conclude that one of ordinary skill in the art would have been led to modify the fermentation substrate of the claimed microorganism based on the mutants taught by Gibson. Absent a factual basis or sound scientific reasoning to support her position, we conclude that the rejections are improperly based on unsupported generalities. ***In re Freed***, 425 F.2d 785, 788, 165 USPQ 570, 572 (CCPA 1970); ***In re Warner***, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), ***cert. denied***, 389 U.S. 1057 (1968). ("The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may *doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply the deficiencies in its factual basis.")(Emphasis in original.)

Accordingly, the § 103 rejection over Gibson is reversed.

Other Issues

As a final note, we direct attention to the appellants' admission on p. 2 of the specification that the present ***S. avermitilis*** mutants are identical to the mutants described in continuations of U.S. patent application 107,825, filed October 13, 1987; now U.S. Patent Nos. 5,525,506 and 5,583,015. We find

that the referenced patents show the use of the present mutants to produce avermectins using a process similar to that described in claim 10. The method disclosed in the patents, however, differ from the present method in that an alpha-branched carboxylic acid is employed in the fermentation process, rather than a non-alpha-branched carboxylic acid. Therefore, on return of this application to the examining corps, the examiner should consider whether the present invention would have been obvious to one of ordinary skill in the art in view of all other relevant prior art and the method of producing avermectin by fermenting ***S. avermitilis*** ATCC 53567 or ***S. avermitilis*** ATCC 53568 described in U.S. Patent No. 5,525,506 and/or 5,583,015.

Reversed

WILLIAM F. SMITH
Administrative Patent Judge

TEDDY S. GRON
Administrative Patent Judge

JOAN ELLIS
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 93-1807
Application 07/647,674

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Pfizer Inc.,
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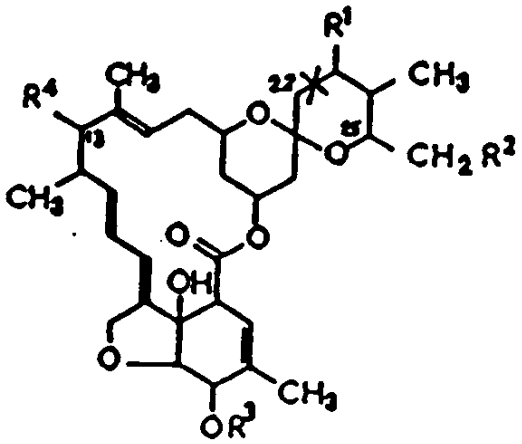
Groton, CT 06340

JE/cam

APPENDIX

10. A process for preparing a compound of the formula



(I)

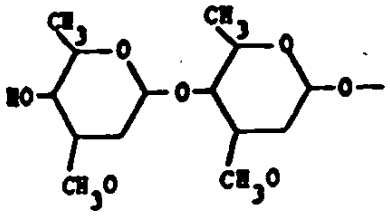
wherein X represents a single or double bond; R^1 is OH; provided that when X is a single bond, R^1 is OH, and when X is a double bond, R^1 is absent;

R^2 is H, C_1-C_8 alkyl, C_2-C_8 alkenyl, C_2-C_8 alkynyl, alkoxyalkyl or alkylthioalkyl containing from 1 to 6 carbon atoms in each alkyl or alkoxy group, wherein any of said alkyl, alkoxy alkenyl or alkynyl groups may be substituted by one or more halo atoms; or a C_3-C_8 cycloalkyl or C_5-C_8 cycloalkenyl group, either of which may be substituted by methylene or one or more C_1-C_4 alkyl groups or halo atoms; or a 3 to 6 membered

oxygen or sulphur containing heterocyclic ring which may be saturated, or fully or partially unsaturated and which may be substituted by one or more C_1-C_4 alkyl groups or halo atoms; or a group of the formula SR^5 wherein R^5 is C_1-C_8 alkyl, C_2-C_8 alkenyl, C_2-C_8 alkynyl, C_3-C_8 cycloalkyl, C_5-C_8 cycloalkenyl, phenyl or substituted phenyl wherein the substituent is C_1-C_4 alkyl, C_1-C_4 alkoxy or halo, or a 3 to 6 membered oxygen or sulphur containing heterocyclic ring which may be saturated, or fully or partially unsaturated and which may be substituted by one or more C_1-C_4 alkyl groups or halo atoms;

R^3 is hydrogen or methyl;

and R^4 is a 4'-(alpha-L-oleandrosyl)-alpha-L-oleandrosyloxy group of the formula



which comprises fermenting a Streptomyces avermitilis mutant organism ATCC 53567 or 53568, in the presence of a carboxylic acid of the formula $R^2CH_2CO_2H$, wherein R^2 is as previously defined, or a salt, ester, or amide thereof or oxidative precursor therefor, and isolating the compound of formula (I).